UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,781	03/31/2006	Robert Savit	UM-09752	9565
	72960 7590 06/25/2008 Casimir Jones, S.C.		EXAMINER	
440 Science Drive			SAIDI, AZADEH	
Suite 203 Madison, WI 53	3711		ART UNIT	PAPER NUMBER
,			3735	
			MAIL DATE	DELIVERY MODE
			06/25/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)			
Office Action Occurrence	10/527,781	SAVIT ET AL.			
Office Action Summary	Examiner	Art Unit			
	Anita Saidi	3735			
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address			
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).					
Status					
1) Responsive to communication(s) filed on					
	-· action is non-final.				
<i>,</i> —	-				
closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.					
		3 3. 3 . 2 . 3.			
Disposition of Claims					
 4) ☐ Claim(s) 1-21 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 1-21 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and/or election requirement. 					
Application Papers					
 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. 					
Priority under 35 U.S.C. § 119					
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 					
Attachment(s) Notice of References Cited (PTO-892)					

Art Unit: 3735

DETAILED ACTION

Claim Objections

1. Claims 11 and 21 are objected to because of the following informalities: In line 2, "if" appears to be typing error and should be amended to - -of - - . Appropriate correction is required.

Claim Rejections - 35 USC § 112

- 2. The following is a quotation of the second paragraph of 35 U.S.C. 112:
 - The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 3. Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- 4. Claim 14 recites the limitation "said electrodes" in line 1. There is insufficient antecedent basis for this limitation in the claim. The limitation has not been recited in the preceding claims.

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 12-21 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 12 positively claims "a subject". However, the living body is non-statutory subject matter and cannot be positively recited.

Art Unit: 3735

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 8. Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 3,696,808 to Roy et al (Hereinafter "Roy") in view of 5,995,868 to Dorfmeister et al (Hereinafter "Dorfmeister").

In reference to claims 1 and 12:

Roy teaches:

A system and method which is used for brain wave analysis (Abstract of Roy). A first data sensor (31, 48 of Roy) is positioned on the scalp of a subject near the focal point of ictal onset and a second data sensor (32, 49 of Roy) positioned on the scalp of the subject, where the second data sensor is remote from the first data sensor (Fig. 3 and Col. 6, lines 7-17 of Roy). The signals collected from different sides of the brain are filtered and cross correlated in order to determine a correlation coefficient that is indicative of the epileptic seizure (Col. 5, lines 20-68 of Roy). The signals' amplitude

Art Unit: 3735

and phase differences is calculated after the collected signals are passed through a comparator and the ictal onset is predicted by difference in the first marginal predictability value and a second marginal predictability value (102, 103 and Col. 3, lines 40-68 and Col. 5, lines 20-68 of Roy). Roy also teaches that the correlation coefficient is calculated using a non-linear algorithm (Col. 5, lines 25-35 of Roy).

However, Roy fails to teach that:

A processor analyzes the collected data to provide a nonlinear mathematical manipulation of the collected data.

Dorfmeister teaches:

A system (10 of Dorfmeister) and method used for analyzing signals representative of a subject's brain activity in a signal processor (12 of Dorfmeister) for information indicating the subject's current activity state and for predicting a change in the activity state. Dorfmeister teaches that a combination of nonlinear filtering methods is used to perform real-time analysis of the electro-encephalogram (EEG) or electro-corticogram (ECoG) signals from a subject patient for information indicative of or predictive of a seizure, and to complete the needed analysis at least before clinical seizure onset. The system then performs an output task for prevention or abatement of the seizure,

Art Unit: 3735

or for recording pertinent data (Abstract of Dorfmeister). The filters

are used to differentiate between the ictal and non ictal components

of each input signal (Col. 10, lines 16-30 of Dorfmeister).

Therefore it would have been obvious to one having ordinary skill in the art

to use a nonlinear filter similar to the one taught by Dorfmeister in the

brain wave monitoring device and method of Roy to manipulate the input

signals in order to distinguish between ictal and non ictal components of

the input signals to reduce the processing time and increase the accuracy

of the seizure prediction (Col. 4, lines 43-68 of Dorfmeister).

In reference to claims 2 and 13:

The first and second data sensors comprise electrodes (Fig. 4, helmet 30, probes

31 and 32 of Roy).

In reference to claims 3 and 14:

The electrodes record electroencephalogram data from the subject (Col. 1, lines

52-64 of Roy).

In reference to claims 4 and 15:

The processor compares the difference between the first marginal predictability value and the second marginal predictability value (Col. 3, line 40-Col. 4, line 26 and Col. 7, lines 9-40 of Roy).

In reference to claims 5 and 16:

The difference between the first marginal predictability value and the second marginal predictability value decreases indicting ictal onset (Col. 3, line 49-Col. 4, line 26 of Roy).

In reference to claims 6, 8 and 17, 19:

The system and method further comprise a subject warning device configured to receive information from the processor (Col. 9, lines 10-26 and audio or LED or any out put for of warning 34 of Dorfmeister).

In reference to claims 7 and 18:

The information comprises information predictive of an ictal onset (Figs. 8 and 11 of Roy and Col. 9, lines 10-26 of Dorfmeister).

In reference to claim 9:

The processor further comprises a computer readable memory (105, 207 and 208 of Roy and 36 of Dorfmeister).

In reference to claims 10 and 20:

The system and method further comprise an anti-seizure agent (pump and injector 32 and stimulator 28 of Dorfmeister) administering device in communication with the processor, where the anti-seizure agent administering device administers an anti-seizure agent to the subject (Col. 9, lines 10-26 of Drofmeister).

In reference to claims 11 and 21:

The anti-seizure agent administering device is selected from the group consisting of micro pumps and electrical stimuli devices (pump and injector 32 and stimulator 28 of Dorfmeister).

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 4,702,254 to Zabara discloses a neurocybernetic prosthesis. US 5,626,627 to Krystal et al discloses an electroconvulsive therapy method using ictal EEG data as an indicator of ECT seizure adequacy.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anita Saidi whose telephone number is (571)270-3001. The examiner can normally be reached on Monday-Friday 9:30 am - 6:00 pm Est.

Art Unit: 3735

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Charles A. Marmor, II/ Supervisory Patent Examiner Art Unit 3735

/A. S./ Examiner, Art Unit 3735 6/24/2008